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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,636	01/21/2004	Bernard Frank Bishop	PC22004B	3343

28523 7590 02/08/2006

PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
EASTERN POINT ROAD
GROTON, CT 06340

EXAMINER

MCINTOSH III, TRAVISS C

ART UNIT PAPER NUMBER

1623

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/761,636

Applicant(s)

BISHOP, BERNARD FRANK

Examiner

Traviss C. McIntosh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6-8 and 10-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3,4,7,8 and 11 is/are allowed.
- 6) ☒ Claim(s) 6 and 12-19 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Amendment filed November 1, 2005 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 1, 6, 7, 13-17, and 19 have been amended.

Claims 2, 5, and 9 have been canceled.

Remarks drawn to rejections of Office Action mailed July 1, 2005 include:

Claim objections: which have been overcome by applicant's amendments and have been withdrawn.

112 1st paragraph rejections: which have been overcome in part, and thus have been withdrawn in part.

112 2nd paragraph rejections: which have been maintained for reasons of record.

103(a) rejection: which has been overcome by applicant's arguments and has been withdrawn.

An action on the merits of claims 1, 3-4, 6-8, and 10-19 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

Claim Objections

Claim 10 is objected to because of the following informalities: in line 2, there is a spelling error wherein applicants stated “said **either**”, which should read “said **ether**”.

Appropriate correction is required.

Claim 19 is objected to because of the following informalities: in the 1st line, there is a spelling error wherein applicants stated “treatment of prophylaxis”, which should read “treatment **or** prophylaxis”. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The rejection of claims 13-18 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of flea, heartworm, and tapeworm infections using praziquantel and selamectin, does not reasonably provide enablement for prevention of the same, is maintained for reasons of record. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The breadth of the claims - The nature of the invention

Claim 13 of the instant application is drawn to a method for preventing and treating flea, heartworm, and tapeworm infections using praziquantel and selamectin. Claims 14-17 provide various dosing regimens and claim 18 provides the method is to be practiced on a cat.

The state of the prior art

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Selamectin and praziquantel are both known to have efficacy as an agent to control ectoparasite and helminth infections. However, efficacy studies in dogs and cats showed that selamectin provides therapeutic and persistent efficacy against fleas, therapeutic efficacy against gastrointestinal nematodes, and prophylactic activity against heartworms in dogs (see Bishop et al., Veterinary Parasitology, 91, pp. 163-176, 2000, specifically page 174, first paragraph). As such, prophylaxis against fleas, heartworms, and tapeworms is not recognized in the art.

The level of predictability in the art

The examiner acknowledges the probability and predictability that selamectin and praziquantel would have efficacy in treatment, however the art is silent with regard to the predictability of the formulation have preventative efficacy as asserted for fleas, heartworm, and tapeworm.

The amount of direction provided by the inventor

The instant specification is not seen to provide adequate guidance which would allow the skilled artisan to extrapolate from the disclosure and examples provided to use the claimed method commensurate in the scope with the instant claims. There is a lack of data and examples which adequately represent the scope of claim as written.

The existence of working examples

The working examples set forth in the instant specification are directed to the use of praziquantel and selamectin in various experiments. There has not been provided sufficient evidence which would warrant the skilled artisan to accept the data and information provided in the working examples as correlative proof that the formulation as set forth would have the preventative efficacy as asserted.

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The quantity of experimentation needed to make and use the invention based on the content of the disclosure

Indeed, in view of the information set forth supra, the instant disclosure is not seen to be sufficient to enable for prevention of fleas, heartworm, and tapeworm. One skilled in the art could not use the entire scope of the claimed invention without undue experimentation. One skilled in the art would be confronted with an undue burden of experimentation to prepare, characterize, and test the formulation to determine if indeed the had preventative efficacy as asserted.

It is noted that applicants failed to address this rejection in their response. Applicants had amended their claims to overcome the 112 1st rejection over the scope of compounds which was made, but did not address this enablement rejection regarding prevention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 6 and 12-18 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained for reasons of record.

Claim 6 is indefinite wherein the inclusion of parenthetical phrases leaves ambiguity and uncertainty as to whether the contents inside the parenthesis are intended as being that which applicant intends as their invention. Clarity is respectfully requested. Removal of parentheses and replacing with commas will obviate this rejection. It is noted that applicants acknowledged

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this rejection, and stated that “the amended claims now remove any such uncertainty”, however, applicants did not amend the claims to remove the parenthesis. As such, this rejection is maintained.

Claim 12 is also indefinite for the inclusion of the parenthetical phrase “(at less than 0.1% w/v)” in line 7. It is unclear if applicants intend this as their invention or not. Removal of the parenthesis would be seen to obviate this rejection. It is noted that applicants acknowledged this rejection, and stated that “the amended claims now remove any such uncertainty”, however, applicants did not amend the claims to remove the parenthesis. As such, this rejection is maintained.

Claim 13 is indefinite wherein the claim is drawn to a method of “treatment **and** prophylaxis” of parasitic infections. However, it is unclear how an infection can be both treated and prevented. If a subject has had preventative therapy, then there is no need for subsequent treatment. Changing the “and” to “or” would be seen to obviate the instant rejection. It is noted that applicants acknowledged this rejection, and stated that “the amended claims now remove any such uncertainty”, however, applicants did not amend the claims to correct the error. As such, this rejection is maintained.

All claims which depend from an indefinite claim are also indefinite. *Ex parte Cordova, 10 U.S.P.Q. 2d 1949, 1952 (P.T.O. Bd. App. 1989).*

Conclusion

Claims 1, 3-4, 7-8, and 11 are allowed. Claim 10 would be allowed if the spelling correction was made as indicated above.

The prior art is not seen to teach or fairly suggest the specific combination of selamectin and praziquantel in topical formulations as instantly claimed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

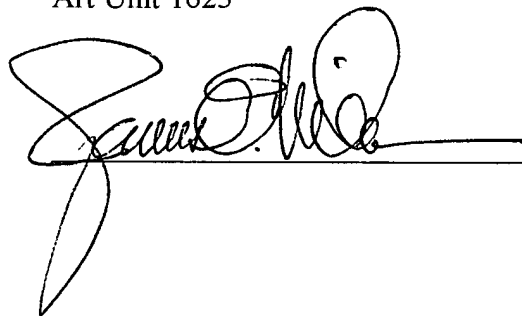
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Traviss C. McIntosh III
February 3, 2006

James O. Wilson
Supervisory Patent Examiner
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A handwritten signature in black ink, appearing to read "James O. Wilson", is written over a horizontal line. The signature is stylized with large loops and a long, sweeping underline that extends to the right.